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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/001,469
Filing Date	October 31, 2001
First Named Inventor	Aya JAKOBOVITS
Art Unit	1642
Examiner Name	Minh-Tam B. Davis
Total Number of Pages in This Submission: 171	Attorney Docket Number: 511582002420

ENCLOSURES (*Check all that apply*)

- [ ] Fee Transmittal Form (
  - [ ] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) (please Identify below):

1. Petition Fee Transmittal (1 page in duplicate)
2. Petition Under 37 C.F.R. § 1.181 Requesting Entry of An Amendment After Final with Appendices A, B, and C (14 pages
3. Postcard Return Receipt

Remarks

Customer No. 36327

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	MORRISON & FOERSTER LLP		
Signature	Kate H. Murashige		
Printed name	Kate H. Murashige		
Date	August 10, 2005	Reg. No.	29,959

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: MS Petitions, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: August 10, 2005 Signature: Stacey Myers (Stacey Myers)

PTO/SB/17p (11-04)
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PETITION FEE
Under 37 CFR 1.17(f), (g) & (h)
TRANSMITTAL

(Fees are subject to annual revision)

Send completed form to:
MS AF
Commissioner for Patents
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Alexandria, VA 22313-1450

Application Number	10/001,469
Filing Date	October 31, 2001
First Named Inventor	Aya JAKOBOVITS
Art Unit	1642
Examiner Name	Minh-Tam B. Davis
Attorney Docket Number	511582002420

Enclosed is a petition filed under 37 CFR 1.181 **that requires a processing fee (37 CFR 1.17(f)), (g), or (h)). Payment of $** 400.00 **is enclosed.**

This form should be included with the above-mentioned petition and faxed or mailed to the Office using the appropriate Mail Stop (e.g., Mail Stop Petition), if applicable. *For transmittal of processing fees under 37 CFR 1.17(i), see form PTO/SB/17i.*

Payment of Fees (small entity amounts are NOT available for the petition fees).

[X] The Commissioner is hereby authorized to charge the following fees to Deposit Account No. 03-1952 :
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Enclose a duplicative copy of this form for fee processing.

[ ] Check in the amount of $ _____ is enclosed.

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Petition Fees under 37 CFR 1.17(f): Fee $400 Fee Code 1462

For petitions filed under:
§ 1.53(e) – to accord a filing date.
§ 1.57(a) – to accord a filing date.
§ 1.182 – for decision on a question not specifically provided for.
§ 1.183 – to suspend the rules.
§ 1.378(e) – for reconsideration of decision on petition refusing to accept delayed payment of maintenance fee in an expired patent.
§ 1.741(b) – to accord a filing date to an application under § 1.740 for extension of a patent term.

Petition Fees under 37 CFR 1.17(g): Fee $200 Fee Code 1463

For petitions filed under:
§ 1.12 – for access to an assignment record.
§ 1.14 – for access to an application.
§ 1.47 – for filing by other than all the inventors or a person not the inventor.
§ 1.59 – for expungement of information.
§ 1.103(a) – to suspend action in an application.
§ 1.136(b) – for review of a request for extension of time when the provisions of section 1.136(a) are not available.
§ 1.295 – for review of refusal to publish a statutory invention registration.
§ 1.296 – to withdraw a request for publication of a statutory invention registration filed on or after the date the notice of intent to publish issued.
§ 1.377 – for review of decision refusing to accept and record payment of a maintenance fee filed prior to expiration of a patent.
§ 1.550(c) – for patent owner requests for extension of time in ex parte reexamination proceedings.
§ 1.956 – for patent owner requests for extension of time in inter partes reexamination proceedings.
§ 5.12 – for expedited handling of a foreign filing license.
§ 5.15 – for changing the scope of a license.
§ 5.25 – for retroactive license.

Petition Fees under 37 CFR 1.17(h): Fee $130 Fee Code 1464

For petitions filed under:
§ 1.19(g) – to request documents in a form other than that provided in this part.
§ 1.84 – for accepting color drawings or photographs.
§ 1.91 – for entry of a model or exhibit.
§ 1.102(d) – to make an application special.
§ 1.138(c) – to expressly abandon an application to avoid publication.
§ 1.313 – to withdraw an application from issue.
§ 1.314 – to defer issuance of a patent.

Kate H. Murashige
Signature

August 10, 2005
Date

Kate H. Murashige
Typed or printed name

29,959
Registration No., if applicable

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Dated: August 10, 2005 Signature: _____ (Stacey Myers)

Docket No.: 511582002420
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Aya JAKOBOVITS et al.

Application No.: 10/001,469 Confirmation No.: 3304

Filed: October 31, 2001 Art Unit: 1642

For: NUCLEIC ACID AND CORRESPONDING PROTEIN ENTITLED 101P3A11 USEFUL IN TREATMENT AND DETECTION OF CANCER

Examiner: Minh-Tam B. Davis

PETITION UNDER 37 C.F.R. § 1.181
REQUESTING ENTRY OF AN AMENDMENT AFTER FINAL

MS Petitions
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In an Advisory Action mailed 17 June 2005, the Examiner refused to enter a proposed amendment submitted in a response mailed 16 February 2005 to final rejection. Accordingly, this petition is timely filed.

The proposed amendment was completely responsive to a rejection under 35 U.S.C. § 112, paragraph 2, and to an objection to claim wording. The refusal to enter the amendment was based on the assertion that new issues were raised by the phrase "or the downstream signaling effects thereof." No reason was given why this language would require new 112 first and second paragraph rejections (see Exhibit A - page 2 of the Advisory), and applicants are unable to determine why this

should be the case, since this phrase is a narrower form of "activity" - a term already present in the claims.

A copy of the proposed amendment is attached as Exhibit B.

On page 2 of the final rejection, attached as Exhibit C for convenience, an objection was raised to the claims as unclear with regard to the referent of the SEQ ID NO. The amendment to the claims makes the suggested clarification. There was also a rejection under 35 U.S.C. § 112, second paragraph, because claims 48, 50 and 54 were indefinite for the use of the language "activity" in claim 48 and stated that it was not clear what type of activity is referred to.

The proposed amendment is directly responsive to this objection. It defines this activity as comprising cAMP accumulation mediated by the protein in question or the downstream signaling effects thereof. As pointed out in the accompanying remarks, there is no issue here raised. Clearly "downstream signaling effects" raises no more issues that the more general term "activity." Further, as noted, a description of these effects is found on page 106 of the substitute specification and the specific downstream effect identified in claim 55 is substantiated by working examples. No objection was raised to the phrase "cAMP accumulation," as that appeared in previously pending claim 56 which is now canceled as redundant.

It is applicants' position that no new issues are in fact raised by substituting the more precise term "downstream effects of cAMP accumulation" than the less precise term "activity." As the Advisory Action indicates that the objection and the 35 U.S.C. § 112, second paragraph, rejection are maintained because the amendment is not entered, clearly entry of the amendment would simplify the issues on appeal. The issues on appeal are limited to 35 U.S.C. §§ 112/101 issues which will be the subject of a brief on appeal.

In order to expedite prosecution of this case, and limit the issue on appeal to the substantive rejection, applicants respectfully request that the proposed amendment to the claims be entered.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 511582002420.

Respectfully submitted,

Dated: August 9, 2005 By: Kate H. Murashige

Kate H. Murashige
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DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment of 02/22/05 is not and will not be entered, because it raises new issues. That is the addition of the language "downstream signaling effects thereof" requires new 112, second and first paragraph rejections.

The following are answers to applicant's arguments.

OBJECTION

Claims 48, 50, 54-56 remain objected to, because the amendment of claim 48 to obviated this objection is not and will not be entered.

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH

Claims 48, 50, 54 remain rejected under 112, second paragraph, because the amendment of claim 48 to obviate this rejection is not and will not be entered.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT

1. If claims 48, 50, 54-56 were to be entered, rejection under 35 USC 112, first paragraph of claims 48, 50, 54-56 pertaining to lack of enablement for a method for identify an agent that decrease the activity of the 101P3A11 protein of SEQ ID NO:2866, wherein said activity comprises 101P3A11-mediated cAMP accumulation or

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Dated: February 16, 2005 Signature: (Rebecca McElroy)

Docket No.: 511582002420
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Aya JAKOBOVITS et al.

Application No.: 10/001,469

Filed: October 31, 2001

For: NUCLEIC ACID AND CORRESPONDING PROTEIN ENTITLED 101P3A11 USEFUL IN TREATMENT AND DETECTION OF CANCER

Confirmation No. 3304

Art Unit: 1642

Examiner: Minh-Tam B. Davis

EXPEDITED PROCEDURE -- EXAMINING GROUP 1642

AMENDMENT UNDER 37 C.F.R. § 1.116

MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to an Office Action herein, mailed 16 December 2004, time for response to which was set to expire 16 March 2005. An early response for expedited consideration is being filed by the two-month date of 16 February 2005. Claims 48, 50 and 54-56, were rejected on formal grounds; there is no rejection over the art. Careful consideration has been given to the grounds for rejection, and the following amendment and discussion are offered in response. Reconsideration is respectfully requested.

CLAIM AMENDMENTS

1-47. (canceled)

48. (currently amended): A method to identify an agent that decreases 101P3A11 protein activity, comprising:

providing a first sample of cells and a second sample of cells, wherein the cells of each sample express 101P3A11 ~~(SEQ ID NO:2866)~~;

contacting the first sample with a candidate compound and

~~observing~~ measuring 101P3A11 protein activity in the first sample with the candidate compound;

~~observing~~ measuring 101P3A11 protein activity in the second sample, wherein the second sample has not been contacted with said candidate compound;

comparing the ~~observed~~ measured 101P3A11 protein activity in said first and second samples;

whereby a diminution in the 101P3A11 protein activity in said first sample as compared to said second sample identifies said compound as an agent that decreases 101P3A11 protein activity;

wherein 101P3A11 protein is SEQ ID NO: 2866; and

wherein said activity comprises 101P3A11-mediated cAMP accumulation or the downstream signaling effects thereof.

49. (canceled)

50. (previously presented): The method of claim 48, wherein said cells have been modified to contain an expression system for said 101P3A11 protein.

51-53. (canceled)

54. (previously presented): The method of claim 48, wherein the candidate compound is an antibody that binds specifically to the 101P3A11 protein.

55. (currently amended): The method of claim 48, wherein measuring the 101P3A11 activity comprises measuring a downstream signaling effect which is 101P3A11-mediated ERK phosphorylation.

56. (canceled)

REMARKS

The claims have been amended to obviate rejections under 35 U.S.C. § 112, paragraph 2, and certain of the rejections under 35 U.S.C. § 112, paragraph 1. Claim 48 has been amended to clarify that by the term "101P3A11 protein" is meant SEQ ID NO: 2866. In claim 48, also, "observing" has been changed to "measuring" as being more consistent with the overall claim structure. Further, claim 48 has been amended to insert the limitation of claim 56 to specify that the activity to be measured is cAMP accumulation, which in turn has downstream signaling effects. A description of these downstream signaling effects is found on page 106 of the substitute specification. As noted, it has been established in working Example 40 that the activity of 101P3A11 protein comprises an increase in cAMP accumulation (see page 106, line 38-page 107, line 6). This example further confirms, experimentally, that the effect of cyclic AMP can be exhibited in the results of further downstream signaling, one of which is phosphorylation of ERK. There is no doubt of these results as they are described in working examples. Thus, the amendments to the claims are fully supported by the specification and are made specifically in response to the rejections now outstanding. Therefore, entry of the amendment, though made after final, is respectfully requested.

The Rejections

The objection to the claim language and the rejection under 35 U.S.C. § 112, second paragraph, as well as the second part of the rejection under 35 U.S.C. § 112, first paragraph, have been overcome by amendment. It is clarified, now, that "101P3A11 protein" refers solely to SEQ ID NO: 2866, which was the intent all along. This overcomes the objection and the second portion of the rejection under 35 U.S.C. § 112, paragraph 1. The activity of the protein has also been

defined in claim 48 by inserting the limitations of claim 56 which was not included in the rejection under paragraph 2. The inclusion of downstream signaling effects is fully supported by the specification on page 107 and by existing claim 55 which has been amended merely to conform its wording to the reworded claim 48.

Accordingly, the only outstanding rejection is with respect to enablement as set forth on pages 3-5 of the Office action. This rejection was applied to all claims; as applied to claim 48, a portion of this has been overcome by defining the protein activity to which the claim refers. Accordingly, the rejection as applied to claim 48 on this basis appears moot.

As to the remainder of the rejection, this does not appear to be based on any assertion that one would not know how to measure the protein activity of 101P3A11 based on the teachings of the specification. There is no assertion that the specification fails to teach one how actually to perform the steps in the method claimed. Rather, the Office questions whether the candidate identified by the claimed method would itself be of any value – the Office states that "one would not know how to use the agents identified by the claimed method."

This is clearly not so. The specification teaches how to use the agents thus identified. At page 43, line 33, it is clearly stated that "therapeutic approaches that inhibit the activity of the 101P3A11 protein are useful for patients suffering from a cancer that expresses 101P3A11." In particular, antibodies which inhibit the activity of this protein are stated to be useful, in support specifically, of claim 54. (See page 47, beginning at line 15.) The use of antibodies as inhibitors has been demonstrated by Declaration in copending application 10/147,368 to inhibit the growth of cancers that express 101P3A11. Antibodies to this protein are shown to inhibit the growth of human prostate cancer xenographs in mice. A copy of the declaration submitted in that case along with the experimental results is enclosed. Applicants wish to make clear that these antibodies are to

the same protein as that of the present claims. The relevant sequence in 10/147,368 is SEQ ID NO: 28. This is identical to SEQ ID NO: 2866 in the present application except that SEQ ID NO: 2866 shows an extra methionine at the N-terminus which behaves as a possible superfluous start codon, so that SEQ ID NO: 2866 has 318 amino acids. The 101P3A11 protein itself has 317 amino acids and is lacking the extra N-terminal methionine, as noted on page 6 of the substitute specification which states that Figure 3 shows the amino acid sequence of 101P3A11 and that this protein has 317 amino acids. That figure is, however, referenced to SEQ ID NO: 2866. If necessary, a substitute sequence listing can be submitted showing 101P3A11 protein as having 317 amino acids. In any event, it is not relevant for purposes of the present claims since the activity of the protein will be the same regardless of the presence or absence of this N-terminal methionine.

In summary, the declaration submitted in application 10/147,368 refers to the ability of antibodies directed against the same protein as that whose activity is to be measured according to the present claims to inhibit tumor growth.

It appears that the rejection is simply based on doubts that the method, which itself is clearly enabled, would identify substances that are successful in treating cancers that express 101P3A11. It will be noted that the claims do not require such success, they are simply directed to a method to identify an agent that decreases this protein activity which may or may not turn out to be successful in treating cancers. This is no different from any screening assay; screening assays are extremely useful in identifying compounds that are candidates for treatment; only a small fraction of these candidates turn out to be viable therapeutics. This does not render the screening methods useless; if they were useless, pharmaceutical companies would not spend millions of dollars annually to conduct them, and there would be no way to select a small number of compounds for further testing.

The Office cites some papers showing problems that might affect the predictive value of the assay. The first paper cited, Chang, *et al., Leukemia* (2003) 17:1263-1293, actually supports the position taken by applicants. The paper states, as the Office says it does, that the signaling pathway which ends with ERK mediates transcription. The fact that the manner of mediation is not completely understood, or that this particular pathway may not be the only one relevant to cancers, does not destroy the utility of the assay. Instead, this paper takes the assertions of applicants one step further toward verification of utility.

The Office then cites Hummler, E., *et al., PNAS* (1994) 91:5647-5661. This paper indicates that signaling systems are complex and interrelated and that there is not a linear relationship between cAMP and transcriptional regulation. Why this is relevant to the present claims is unclear. Applicants are well aware that regulation of transcription is complex and that the ability of a candidate compound to inhibit cAMP accumulation mediated by 101P3A11 does not have a disclosed linear pathway to inhibition of cancer growth. However, this is irrelevant to the utility of the method of the invention. As stated by the Court in *Fromson v. Advance Offset Plate, Inc.*, 720 F2d 1565, 219 USPQ 1137 (Fed. Cir. 1983), "It is axiomatic that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests" citing *Diamond Rubber Co. v. Consolidated Rubber Tire Co.*, 220 US 428 (S.Ct. 1911).

Thus, it is quite clear that applicants need not describe the exact mechanisms whereby inhibition of the activity of 101P3A11 protein might result in the inhibition of cancer growth.

Also cited by the Office is Xu, *et al., FASEB J.* (2001) 15:A313 for the proposition that there are regulatory systems which might overcome perturbations imposed on a system. Again, this is common knowledge and, applicants believe, irrelevant to the invention which rests on the concept that high levels of 101P3A11 protein are found in cancers and that this protein has a defined activity

which can be measured. It stands to reason that if the protein is at high levels in cancer, its activity is probably contributing to the growth of the cancer and therefore inhibition of this activity should inhibit cancer growth. This is not a proposition contrary to general scientific principles.

Respectfully, the Office appears to require a level of certainty with respect to efficacy that is not required by the law. Perhaps relevant to this issue is the decision in *Moleculon Research Corp. v. CBS, Inc.*, 793 F2d 1261, 229 USPQ 805 (Fed. Cir. 1986) where claims to a method of solving a Rubik's Cube puzzle were asserted to be un-useful because they do not teach the complicated method of solving it. As stated by the Court, the claims were directed to a method for restoring a preselected pattern using a general approach for solving the puzzle. The Court stated that neither the claims nor the disclosure need set forth a particular series of moves to solve the puzzle as these moves depend on how the preselected pattern was randomized and there may be more than one sequence of steps. All the claims needed to do, apparently, was to claim an approach.

Further, as stated by the Court in *Envirotech Corp. v. Al George, Inc.*, 730 F2d 753, 221 USPQ 473 (Fed. Cir. 1984), the fact that an invention has only limited utility and is only operable in certain applications is not grounds for finding a lack of utility citing *Raytheon Co. v. Roper Corp.*, 724 F2d 951, 220 USPQ 592 (Fed. Cir. 1983) among other cases. As stated, only some degree of utility is sufficient for patentability citing *E.I. DuPont de Nemours v. Berkley and Co.*, 620 F2d 1247, 205 USPQ 1 (8th Cir. 1980). "The defense of non-utility cannot be sustained without proof of total incapacity."

Total incapacity is far from the case here. Data are supplied which demonstrate that the activity of the 101P3A11 protein is elevated in cells that express it and that cells that express this protein characterize various cancer cells. This appears sufficient basis to assert the utility of the claimed method which is designed to provide useful candidates for cancer therapy.

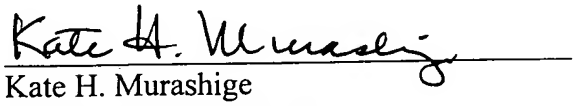
For these reasons, the rejection for lack of enablement may clearly be withdrawn.

Conclusion

There is no assertion that the specification does not enable one to practice the invention as claimed, although the rejection is stated in those terms. The rejection appears based entirely on the assertion that by performing the method of the invention the compounds identified as successful inhibitors would not be useful. This is contrary to the teachings of the specification which demonstrate that such inhibitors are good candidates as anticancer drugs. This is further supported by the enclosed declaration copy from copending application 10/147,368 which demonstrates that antibodies to this protein do indeed inhibit cancer growth. Accordingly, it is believed that claims 48, 50 and 54-55 are in a position for allowance and passage of these claims to issue is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 511582002420.

Respectfully submitted,

Dated: February 16, 2005 By: 

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DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claim 53, and adds new claims 54-56, that are related to claims 48, 50 and are not new matter.

Accordingly, claims 48, 50, 54-56 are examined in the instant application.

The following are the remaining rejections.

OBJECTION

Claims 48, 50, 54-56 are objected to for the use of the language "101P3A11(SEQ ID NO:2866)" in claim 48. It is not clear whether 101P3A11 is the sequence of SEQ ID NO:2866, or whether SEQ ID NO:2866 is one among different 1013A11 proteins. This objection could be obviated by replacing "101P3A11(SEQ ID NO:2866)", for example, with "the 101P3A11 which is SEQ ID NO:2866".

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH, NEW REJECTION

Claims 48, 50, 54 are indefinite for the use of the language "activity" in claim 48, which does not set forth the metes and bound of the claimed invention. It is not clear what type of activity is referred to.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT